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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,477	04/20/2004	Swee Hin Tcoh	NUS-8 DIV I	4933
7590 Mark J. Pandiscio Pandiscio & Pandiscio 470 Totten Pond Road Waltham, MA 02154		10/16/2007	EXAMINER WOODWARD, CHERIE MICHELLE	
			ART UNIT 1647	PAPER NUMBER
			MAIL DATE 10/16/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,477	TEOH ET AL.	
	Examiner	Art Unit	
	Cherie M. Woodward	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 August 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 40,43,44,48 and 50-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 40,43,44,48 and 50-56 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/30/2007</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Formal Matters

1. Applicant's Response, filed 13 August 2007, is acknowledged and entered. Claims 1-39, 41, 42, 45, 46, 47, and 49 have been cancelled by Applicant. New claims 50-56 have been added. Claims 40, 43, 44, 48, and 50-56 are pending and under examination.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 30 April 2007 has been considered by the Examiner. A signed copy is attached hereto.

Objections/Rejections Withdrawn

3. The objection regarding the use of the trademarks in the specification, is withdrawn in light of Applicant's amendments.
4. Rejections over cancelled claims 41, 42, 45, 46, and 47 are withdrawn as moot, in light of Applicant's cancellation of the claims.
5. The rejection of claims 40, 43, 44, and 48 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, is withdrawn in light of Applicant's amendments.
6. The rejection of claims 40 and 48 under 35 U.S.C. 112, second paragraph, as being indefinite regarding the confusing intersection of angles and degrees, is withdrawn in light of Applicant's amendments.
7. The rejection of claims 40, 43, and 44 under 35 U.S.C. 102(e) as being anticipated by Richter et al., US Patent 6,280,478 (28 August 2001), benefit to 4 January 1999), is withdrawn as moot in light of the new claim rejection, below.

Claim Rejections Maintained***Claim Rejections - 35 USC § 112, First Paragraph******Written Description***

8. Claims 40, 43, 44, and 48 remain rejected and new claims 50-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record and the reasons set forth below.

Applicant argues that the claim amendments have overcome the rejection. Applicant's arguments have been fully considered, but they are not persuasive.

Vas-Cath Inc. V. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), states that Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117). A review of the language of the claim indicates that these claims are drawn to a genus, i.e., a three dimensional apparatus for use in tissue engineering having interconnectivity between channels throughout the scaffold structure wherein the orientation is in triangles, five-sided polygons, or different lay-down patterns.

There is a single species of the claimed genus disclosed that is within the scope of the claimed genus, i.e. a scaffold fabricated using PCL and PCL/HA filaments with a FDM 3D MODELER rapid prototyping system from STRATASYS, INC., with triangular and polygonal pores, with a specific offset yield strength, specific lay-down pattern of angles, specific scaffold dimensions, specific porosity, produced with a specific sized extruder tip, generated at a specific temperature, and with specific requirements for compression (see Example 1, p. 48-54 of the disclosure). The disclosure of a single species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species that are not further described. The claims use the language "comprising" and as such, are not limited only to the requirements set forth in the claims and the claims encompass numerous species that are not otherwise defined in the claims or the specification. The claimed scaffold apparatus comprises any scaffold structure comprising at least three-dimensional horizontal layers and vertical walls of melt extrusion filament comprising at least one of PCL and PCL/HA where the lay-down patterns form horizontally disposed triangles (claim 40) or five-sided polygons (claim 48). No specific offset yield strength, scaffold dimensions, porosity, extruder tip size (which makes the dimensions of the filaments variable), compression requirements, or limitations on other components that may be included in the scaffold apparatus are set forth in the claims such that they would otherwise limit the genera of apparatus'

Art Unit: 1647

encompassed by the claims. The limitations of Example 1 of the specification are not fully set forth in the instant claims. While “examples explicitly covering the full scope of the claim language” typically will not be required, a sufficient number of representative species must be included to “demonstrate that the patentee possessed the full scope of the [claimed] invention.” *Lizardtech v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345, 76 USPQ2d 1724, 1732 (Fed. Cir. 2005).

Additionally, the criticality of the lay-down pattern limitation of amended claims 40 and 48 is called into question by new claims 52-55. Claims 52 and 54, which are dependent on claims 40 and 48, recite the claimed genus of scaffolds with a different lay-down pattern. Similarly, claims 53 and 55 recite the claimed genus of scaffolds with different lay down patterns where the total porosity of the different lay-down patterns is substantially identical. The recitation of the limitation “different lay down patterns” is not described in the specification or the claims. If the lay-down pattern shape (i.e. triangular or five-sided polygonal pattern) is to be considered a critical elements of the claimed invention, such that the lay-down pattern is presumably the argued basis for patentability (see Remarks, p. 2, labeled p. 14), the recitation of “different lay-down patterns” in the claims not only renders the pattern lay-down limitations of claims 40 and 48 moot, but also raises the question of whether the lay-down pattern is a critical limitation of the claimed invention. Because Applicant simultaneously argues mutually exclusive limitations – both for specific lay-down patterns and general lay-down patterns, which also arguing that the lay-down pattern distinguished the claims over the prior art, the Examiner cannot lend credence to Applicant’s arguments as to the criticality of the scaffold lay-down pattern.

In the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus, which is a three dimensional apparatus for use in tissue engineering having interconnectivity between channels throughout the scaffold structure where the walls are laid-down in patterns forming horizontally disposed triangles or five-polygons or different lay-down patterns. One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus. Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features (see, *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1895 (Fed. Cir. 2004); accord *Ex Parte Kubin*, 2007-0819, BPAI 31 May 2007, opinion at p. 16, paragraph 1).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1647

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 40, 43, and 44 remain rejected, amended claim 48, and new claims 50-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Cima et al., US Patent 5,518,680 (21 May 1996, benefit to 23 February 1994) for the reasons of record and the reasons set forth below.

Applicant argues that the amendment to the claims introduces limitations not anticipated by the prior art. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that the introduction of the limitation "triangles" in independent claim 40 and "five-sided polygon" in claim 48, as limitations on the lay-down pattern of the claimed scaffold apparatus is limiting such that the art does not anticipate the invention as claimed. The examiner would have been persuaded by this argument because the *ipsa verba* limitation of the lay-down pattern of "triangles" and "five-sided polygon" does not appear in the '680 patent. However, the criticality of the lay-down pattern limitation of amended claims 40 and 48 is called into question by new claims 52-55. Claims 52 and 54, which are dependent on claims 40 and 48, recite the claimed genus of scaffolds with a different lay-down pattern. Similarly, claims 53 and 55 recite the claimed genus of scaffolds with different lay down patterns where the total porosity of the different lay-down patterns is substantially identical. The recitation of the limitation "different lay down patterns" in claims 52-55 is confusing because if the lay-down pattern shape (i.e. triangular or five-sided polygonal pattern) is to be considered a critical elements of the claimed invention, such that the lay-down pattern is presumably the argued basis for patentability (see Remarks, p. 2, labeled p. 14) such that other lay-down patterns are excluded from the scope of the claims, the recitation of "different lay-down patterns" in the claims not only renders the pattern lay-down limitations of claims 40 and 48 moot, but also raises the question of whether the lay-down pattern is a critical limitation of the claimed invention. Because Applicant simultaneously argues mutually exclusive limitations – both for specific lay-down patterns and general lay-down patterns, while also arguing that the lay-down pattern distinguished the claims over the prior art, the Examiner cannot lend credence to Applicant's arguments as to the criticality of the scaffold lay-down pattern. As such, the rejection is maintained.

The '680 patent teaches a customized scaffold structure for use in tissue engineering for an individual patient as claimed, including the use of scanning and fused deposition modeling (FDM) (abstract; column 1, lines 16-28; and column 2, lines 11-13) (compare claims 40 and 48). FDM employing melt extrusion filaments are taught at column 6, lines 8-12 and 18-22, including FDM

Art Unit: 1647

operating in X, Y, and Z axes (column 6, lines 18-22) (compare claims 40 and 48). Polymers to be used include polycaprolactone (PCL) (column 8, line 37) and composites including hydroxyapatite (PCL/HA) (column 1, line 52 and 63) (compare claims 40 and 48). Example 1 (column 14, lines 30-67 to column 15, lines 1-5) teach a bone regeneration matrix comprising three-dimensional multiple layers that comprise complex architectural features and macroscopic shapes, including linear and curved shapes, which can be manipulated by varying the printing instructions (compare claims 40, 43, 44, 48, 52, 53, 54, 55, and 56). Lines 100 microns wide spaced 300 microns center-to-center along the length of a 2cm axis (each line being 200 microns in depth) is taught at column 14, lines 29-31 (compare claims 50-51).

New Claim Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 112, Second Paragraph

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 40, 43, 44, 45, 48, and 50-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant uses the trademarked company name “STRATASYS, INC” and the trade name “FDM 3D MODELER” in claims 40 and 48.

If a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name. See MPEP 2173.05(u).

13. Claims 52-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 52 and 54 recite the claimed genus of scaffolds with a different lay-down pattern. Claims 53 and 55 recite the claimed genus of scaffolds with different lay down patterns where the total porosity of the different lay-down patterns is substantially identical. The recitation of the limitation “different lay down

Art Unit: 1647

patterns" of claims 52 and 54 (and dependent claims 53 and 55) are confusing because if the lay-down pattern shape (i.e. triangular or five-sided polygonal patterns comprising the scaffold apparatus) are to be considered critical elements of the claimed invention, such that the lay-down pattern is the basis for patentability and other lay-down patterns are excluded from the scope of the claims, the recitation of "different lay-down patterns" not only renders the pattern lay-down limitations of claims 40 and 48 moot, but also raises the question of whether the lay-down pattern is a critical limitation of the claimed invention, and hence to the possible patentability of the invention.

14. Claims 52-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 52 and 54 recite the limitation "different lay-down patterns" in line 3. There is insufficient antecedent basis for this limitation in the claim. Claims 40 and 48, upon which claims 52 and 54 depend, recite triangular lay down patterns (claim 40) and five-sided polygon patterns (claim 48). Similarly, claims 53 and 55, which are dependent on claims 52 and 54 respectively, recite limitations as to total porosity, although there is no antecedent basis for the total porosity in independent claims 40 and 48. It is unclear whether Applicant is relying on the spacing of the interconnected channels to provide support for the term "total porosity." If so, then the claims should be clarified to so state.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 1647

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 40, 43, 44, 48, and 50-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cima et al., US Patent 5,518,680 (21 May 1996, benefit to 23 February 1994).

The Examiner finds the following facts:

- a. The claims are drawn to an apparatus for use in tissue engineering.
- b. The '680 patent teaches a customized scaffold structure for use in tissue engineering for an individual patient as claimed, including the use of scanning and fused deposition modeling (FDM) (abstract; column 1, lines 16-28; and column 2, lines 11-13) (compare claims 40 and 48). FDM employing melt extrusion filaments are taught at column 6, lines 8-12 and 18-22, including FDM operating in X, Y, and Z axes (column 6, lines 18-22) (compare claims 40 and 48). Polymers to be used include polycaprolactone (PCL) (column 8, line 37) and composites including hydroxyapatite (PCL/HA) (column 1, line 52 and 63) (compare claims 40 and 48). Example 1 (column 14, lines 30-67 to column 15, lines 1-5) teach a bone regeneration matrix comprising three-dimensional multiple layers that comprise complex architectural features and macroscopic shapes, including linear and curved shapes, which can be manipulated by varying the printing instructions (compare claims 40, 43, 44, 48, 52, 53, 54, 55, and 56). Lines 100 microns wide spaced 300 microns center-to-center along the length of a 2cm axis (each line being 200 microns in depth) is taught at column 14, lines 29-31 (compare claims 50-51).
- c. The '680 patent does not teach a specific triangle or five-sided polygon pattern. However, it does teach that the lay-down patterns can be manipulated by varying the printing instructions (column 14, lines 65-67 to column 15, lines 1-5).

Art Unit: 1647

- d. The level of skill of those in the art encompasses skills in the field of polymer chemistry relating to the construction or generation of scaffold matrices by standard and routine methodologies.
- e. The scope and content of the prior art in the same field of endeavor as that of Applicant's invention, includes a similar and analogous scaffold apparatus and well-known devices for making scaffolds.
- f. There were design incentives or market forces which would have prompted the adaptation of the known scaffold apparatus.
- g. The differences between the claimed invention and that of the prior art were encompassed in known variations or in a principle known in the prior art.
- h. One of ordinary skill in the art, in view of the design incentives or other market forces, could have implemented the claimed variation of the prior art, and the claimed variation would have been predictable to one of ordinary skill in the art.
- i. The prior art contains a base apparatus, device, and known methods of making biocompatible scaffolds, upon which the claimed invention can be seen as an improvement, the improvement being varying lay-down patterns in the scaffold apparatus.
- j. The prior art contains a comparable apparatus (scaffold) that was improved upon in the same way as the instant invention, by incorporating PLC and PLC/HA melt extrusion compositions formed with FDM operating in X, Y, Z axes to form scaffolds with various lay-down patterns.
- k. One of ordinary skill in the art could have applied the known technique of using PLC and PLC/HA melt extrusion compositions formed with FDM operating in X, Y, Z axes to form scaffolds with various lay-down patterns, simply by varying the printing instructions on the FDM modeler machine, and the results would have been predictable to one of ordinary skill in the art.

In view of the facts recited above, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have varied the lay-down patterns of scaffold apparatus' using PLC and PLC/HA melt extrusion compositions formed with FDM operating in X, Y, Z axes to form scaffolds with various lay-down patterns, simply by varying the FDM printing instructions. Design incentives to vary the pattern include variance in the purpose or anatomical placement of the scaffold (for example, differences in mechanical load strength and suture pull-out strength of the scaffold would vary depending on whether the scaffold was placed in or near a weight bearing anatomical part or subjected to

Art Unit: 1647

intense mechanical stresses), improvements in offset yield strength, or improvements in porosity that could affect blood flow or cellular influx into the scaffold. Market forces would have also prompted the need for variations due to the lack of availability of scaffolds for an increasing variety of anatomical structures and competition in the market for product designed to meet specific anatomical and mechanical repair needs. The composition (i.e. PLC and PLC/HA) of the claimed scaffold is old and well known in the art. The only difference between the instant invention and the prior art is the lay-down pattern of the melt extrusion filament used to construct the scaffold apparatus. However, the art clearly teaches that this pattern can be varied, depending on the design and structural needs of the maker. Thus, the variations in pattern lay-down are known variations of the prior art and they would have been predictable to one of skill in the art at the time the invention was made.

20. Claims 40, 43, 44, 48, and 50-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter et al., US Patent 6,280,478 (28 August 2001), benefit to 4 January 1999), in view of Cima et al., US Patent 5,518,680 (21 May 1996, benefit to 23 February 1994).

The Examiner finds the following facts:

- a. The claims are drawn to an apparatus for use in tissue engineering.
- b. The '478 patent teaches a customized three-dimensional, layered, scaffold structure for use in tissue engineering for an individual patient including the aspect of intercrossing filaments stacked in horizontal planes (see abstract; Figures 1 and 2; Examples 1 and 2, columns 3 and 4) (compare claims 40 and 48). The extrusion of the extrudable mixture and the formation of the lattice structure can be effected using known apparatus such as known apparatus for injection molding of particulate materials, known apparatus for solid free form manufacture by means of fused deposition molding of ceramics, known apparatus for three-dimensional printing of ceramics, known apparatus for multiphase jet solidification of ceramics, and/or known apparatus for stereolithography (column 2, lines 9-16) (compare claims 40 and 48). Fused deposition modeling is taught at column 3, line 66 (compare claims 40 and 48). Extrusion compositions comprising hydroxyapatite and polymers or elastomers are taught at column 2, lines 17-29 (compare claims 40 and 48). Interconnected pores or channels are taught at column 1, line 27 (compare claims 40, 43, 44, 48, 50-56). The scaffold with strands creating pores from 0.2mm (200 microns) to 2mm (2000 microns) is taught at column 4, lines 11-16) (compare claims 50-51). Spherical open concavities [pores] of diameter 200 microns to 3000 microns are a

particularly suitable substrate which is capable of inducing new bone formation at the site where the material is implanted, is obtained (column 5, lines 5-10) (compare claims 50-51). Thus, with such features, the material exhibits intrinsic osteoinductivity (column 5, lines 5-10). Linear components and curved components are taught in Figure 1 and column 3, lines 1-34, especially lines 33-34 (compare claims 43, 44, and 56). Components that can extend at any angle between 10 degrees and 90 degrees relative to those of an adjacent component are taught at column 3, lines 21-23 (see also column 4, lines 50-54) (compare claims 40, 43, 44, 48, 50-56). The pore or channels sizes, mechanical strength of the lattice structure, and directional properties of the lattice structure, can readily be modified or optimized for particular applications (column 5, lines 44-47) (compare claims 40, 43, 44, 48, 50-56). The 3D MODELER system from STRATASYS, INC., (Eden Prairie, MN) is taught at column 4, lines 8-9. See also, claims 1-9.

c. The '478 patent does not teach an extrusion composition comprising polycaprolactone (PCL), but it does teach hydroxyapatite composites including elastomers and polymers. The '478 patent also does not teach specific lay-down patterns of triangles or five-sided polygons. However, it does teach that the directional properties of the lattice structure can readily be modified or optimized for particular applications (column 5, lines 44-47).

d. The '680 patent teaches as set forth above, including polymers such as polycaprolactone (PCL) (column 8, line 37) and composites including hydroxyapatite (PCL/HA) (column 1, line 52 and 63) (compare claims 40 and 48).

e. The level of skill of those in the art encompasses skills in the field of polymer chemistry relating to the construction or generation of scaffold matrices by standard and routine methodologies.

f. The scope and content of the prior art in the same field of endeavor as that of Applicant's invention, includes a similar and analogous scaffold apparatus and well-known devices for making scaffolds.

g. There were design incentives or market forces which would have prompted the adaptation of the known scaffold apparatus.

h. The differences between the claimed invention and that of the prior art were encompassed in known variations or in a principle known in the prior art.

i. One of ordinary skill in the art, in view of the design incentives or other market forces, could have implemented the claimed variation of the prior art, and the claimed variation would have been predictable to one of ordinary skill in the art.

Art Unit: 1647

- j. The prior art contains a base apparatus, device, and known methods of making biocompatible scaffolds, upon which the claimed invention can be seen as an improvement, the improvement being varying lay-down patterns in the scaffold apparatus.
- k. The prior art contains a comparable apparatus (scaffold) that was improved upon in the same way as the instant invention, by incorporating PLC and PLC/HA melt extrusion compositions formed with FDM to form scaffolds with various lay-down patterns.
- l. One of ordinary skill in the art could have applied the known technique of using PLC and PLC/HA melt extrusion compositions formed with FDM to form scaffolds with various lay-down patterns, simply by varying the printing instructions on the FDM modeler machine, and the results would have been predictable to one of ordinary skill in the art.
- m. A person of ordinary skill in the art at the time the invention was made would have reasonably know that a polymer used in biomedical scaffold construction includes polycaprolactone (PCL) and composites including hydroxyapatite (PCL/HA). Further, a person of ordinary skill in the art would have been able to make biomedical scaffold apparatuses using hydroxyapatite and composites comprising hydroxyapatite and polymers, such as polycaprolactone using well-known methodologies and protocols, such as the ones taught by the '478 patent or the '680 patent and the resulting structural composition of the scaffold would have been predictable.

In view of the facts recited above, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have varied the lay-down patterns of scaffold apparatus' using PLC and PLC/HA melt extrusion compositions formed with FDM operating in X, Y, Z axes to form scaffolds with various lay-down patterns, simply by varying the FDM printing instructions. Design incentives to vary the pattern include variance in the purpose or anatomical placement of the scaffold (for example, differences in mechanical load strength and suture pull-out strength of the scaffold would vary depending on whether the scaffold was placed in or near a weight bearing anatomical part or subjected to intense mechanical stresses), improvements in offset yield strength, or improvements in porosity that could affect blood flow or cellular influx into the scaffold. Market forces would have also prompted the need for variations due to the lack of availability of scaffolds for an increasing variety of anatomical structures and competition in the market for product designed to meet specific anatomical and mechanical repair needs. The composition (i.e. PLC and PLC/HA) of the claimed scaffold is old and well known in the art. The only difference between the instant invention and the prior art is the lay-down pattern of the

Art Unit: 1647

melt extrusion filament used to construct the scaffold apparatus. However, the art clearly teaches that this pattern can be varied, depending on the design and structural needs of the maker. Thus, the variations in pattern lay-down are known variations of the prior art and they would have been predictable to one of skill in the art at the time the invention was made.

It would have also been obvious to a person of ordinary skill in the art at the time the invention was made to combine the prior art elements according to known methods to yield predictable results. The prior art teaches all of the limitations of the claimed invention. The '680 patent teaches the polymer polycaprolactone (PCL) and composites of PCL and hydroxyapatite (HA) used in biomedical scaffold devices. The '478 patent teaches hydroxyapatite in combination with polymers and elastomers. The person of ordinary skill in the art could have combined the elements as claimed by known methods to produce a biomedical scaffold comprising PCL or PCL/HA as the bioactive material from which the scaffold was constructed.. One of skill in the art would have recognized that the results of the combination of PCL, as the polymer, and HA would have yielded nothing more than predictable results to one of ordinary skill in the art at the time the invention was made.

Conclusion

NO CLAIM IS ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

Art Unit: 1647

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Gary Nickol/

Gary Nickol
Supervisory Patent Examiner, Art Unit 1646